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Richard S. Barth, Esq.
Frishauf, Holtz, Goodman & Chick P.C.
220 Fifth Ave., 16th Fl.
New York, NY 10001-7708

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,288,726

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,288,726, claims of which cover the human drug product EFFIENT® (prasugrel hydrochloride) and methods of using EFFIENT® (prasugrel hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,679 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,679 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 7, 2010 (75 Fed. Reg. 54344). Under 35 U.S.C. § 156(c):

Period of Extension	=	RRP - PGRRP - DD - ½ (TP - PGTP)[1]
	=	2,795 - 0 - 0 - ½ (2,232)
	=	1,679 days (4.6 years)

Since the regulatory review period began November 16, 2001, after the patent issued (February 22, 1994), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

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[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,288,726
Granted:	February 22, 1994
Original Expiration Date[2]:	September 8, 2012
Applicant:	Hiroyuki Koike et al.
Owner of Record:	Daiichi Sankyo Company, Ltd. and Ube Industries, Ltd.
Title:	Tetrahydrothienopyridine Derivatives, Furo and Pyrrolo Analogs Thereof and Their Preparation and Uses For Inhibiting Blood Platelet Aggregation
Product Trade Name:	EFFIENT® (prasugrel hydrochloride)
Term Extended:	1,679 days
Expiration Date of Extension:	April 14, 2017

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: EFFIENT® (prasugrel hydrochloride)
Docket No.: FDA-2010-E-0048